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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

	: Hon. Faith S. Hochberg, U.S.D.J.
	:
	: MDL No. 1479
	: Master File No. 02-1390
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	: **OPINION**
IN RE NEURONTIN ANTITRUST LITIGATION	:
	: Date: August 27, 2009
	:
	: Civil Action Nos.
	: 02-1830 (FSH)
	: 02-2731 (FSH)
	: 02-5583 (FSH)

APPEARANCES:
Jonathan D. Clemente, Esq.
CLEMENTE MUELLER, P.A.
218 Ridgedale Avenue
Cedar Knolls, New Jersey 07927

LIAISON COUNSEL FOR DIRECT PURCHASER CLASS PLAINTIFFS

Barry L. Refsin, Esq.
Steve D. Shadowen, Esq.
HANGLEY ARONCHICK SEGAL & PUDLIN LLP
One Logan Square, 27th Floor
Philadelphia, Pennsylvania 19103

ATTORNEYS FOR PLAINTIFFS CVS PHARMACY, INC., RITE AID CORPORATION, AND RITE AID HDQTRS. CORP.

Richard Kilsheimer, Esq.
KAPLAN, FOX & KILSHEIMER LLP
850 Third Avenue, 14th Floor
New York, New York 10022

ATTORNEYS FOR PLAINTIFF MEIJER, INC.

Adam Steinfeld, Esq.
Bruce Gerstein, Esq.
Brett Cebulash, Esq.
GARVIN, GERSTEIN & FISHER, LLP
1501 Broadway
New York, New York 10036

ATTORNEYS FOR PLAINTIFF LOUSIANA WHOLESALE DRUG CO.

John J. Francis, Jr., Esq.
Michael C. Zogby, Esq.
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, New Jersey 07932

Gerald Sobel, Esq.
Myron Kirschbaum, Esq.
Stephen J. Elliott, Esq.
Peta Gordon, Esq.
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022

Jack. B. Blumenfeld, Esq.
Karen Jacobs Louden, Esq.
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 N. Market Street
P.O. Box 1347
Wilmington, Delaware 19899

ATTORNEYS FOR DEFENDANTS PFIZER INC., AND WARNER-LAMBERT COMPANY LLC

HOCHBERG, District Judge.

This matter comes before the Court upon the consolidated Motion to Dismiss the Direct Purchaser Plaintiffs' Claims (Docket # 90) filed by Defendants Warner-Lambert Company LLC and Pfizer Inc. (collectively, "Warner-Lambert"), pursuant to Fed. R. Civ. P. 12(b)(6). The Court has considered the briefs of the parties, and oral argument held on April 22, 2009.

I. Factual Background

This matter arises from actions brought by direct purchasers of the anti-epilepsy drug gabapentin, which has been marketed by Defendants under the tradename Neurontin since 1994.[1] Plaintiffs assert that Defendants violated federal antitrust laws by using patents for or related to gabapentin to block generic competition for Neurontin. The Judicial Panel on Multidistrict Litigation transferred several related actions to this Court for coordinated and consolidated pretrial proceedings, pursuant to 28 U.S.C. § 1407.[2] Certain facts and allegations underlying this action have been discussed extensively in two Opinions handed down by this Court today in a

[1] This proceeding involves several interrelated Defendants. Pfizer Inc. is a Delaware corporation. Warner-Lambert Company LLC, formerly Warner-Lambert Company, is a Delaware limited liability company, which became a wholly-owned subsidiary of Pfizer Inc. on or about June 19, 2000. Both Defendants are currently in the business of developing, manufacturing, distributing, advertising and selling Neurontin, among other drugs, throughout the United States.

[2] These proceedings were originally transferred to Hon. John C. Lifland, U.S.D.J. on August 15, 2002. They were reassigned to this Court on March 9, 2007.

related matter, *In re Gabapentin Patent Litig.* (No. 00-2931, MDL No. 1384).[3] For purposes of the instant motion, however, the following background is relevant and bears repeating.

A. Warner-Lambert's Gabapentin Patents

Having discovered gabapentin and its usefulness in preventing and limiting epileptic seizures in the 1970s, Warner-Lambert obtained various patents covering the drug and its uses. Warner-Lambert obtained U.S. Patent No. 4,024,175 (the "'175 Patent"), which claimed the chemical molecule gabapentin anhydrous in 1977. The '175 Patent expired in 1994. In 1979, Warner-Lambert obtained U.S. Patent No. 4,087,544 (the "'544 Patent") covering the use of gabapentin to treat epilepsy. The '544 Patent expired in 2000.[4]

Warner-Lambert developed its Neurontin products on the basis of these patents. Following clinical trials, Warner-Lambert submitted New Drug Applications ("NDAs") to the FDA for the use of gabapentin to treat epilepsy. The FDA approved NDA No. 20-235, for gabapentin capsules, on December 30, 1993 and NDA No. 20-882, for gabapentin tablets, on October 9, 1998. Pursuant to these NDAs, Neurontin was only approved for use as an adjunctive therapy for the treatment of epilepsy.

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[3] The Court recommends that this Opinion be read in conjunction with the Opinion deciding Warner-Lambert's Motion to Strike Certain Affirmative Defenses of the Teva, IVAX, and Eon Defendants (the "Teva Opinion") and the Opinion deciding Warner-Lambert's Motion to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims of Purepac Defendants (the "Purepac Opinion") in *In re Gabapentin Patent Litig*. The Court presumes familiarity with the facts and arguments set forth in the Teva and Purepac Opinions as well as with the abbreviations and acronyms used therein. To the extent the facts and arguments in those Opinions are relevant, yet not reiterated in this Opinion, they are incorporated by reference.

[4] The '544 Patent would have expired on May 2, 1995, but its term was extended under 35 U.S.C. § 156 until January 16, 2000. It was subsequently further extended until July 16, 2000 pursuant to the FDA's pediatric exclusivity regulations.

Warner-Lambert filed several Orange Book listings in connection with the development and sale of Neurontin. In January 1992, Warner-Lambert certified that the '175 and '544 Patents covered the formulation, composition and/or method of use of the drug product that was the subject of NDA No. 20-235. Both patents were then listed in the Orange Book. Plaintiffs contend that Neurontin, as it was approved by the FDA, is protected only by these two patents.

In addition to the '175 and '544 Patents, Warner-Lambert has obtained and listed in the Orange Book several other gabapentin-related patents. In the late 1980s, Warner-Lambert applied for a patent covering a monohydrate form of the gabapentin compound in which each gabapentin molecule is associated with one molecule of water.[5] U.S. Patent No. 4,894,476 (the "'476 Patent"), claiming gabapentin monohydrate, issued on January 16, 1990 and expired on May 2, 2008. At about the same time, Warner-Lambert also discovered that gabapentin could be useful in slowing or preventing neurodegeneration. On January 28, 1992, Warner-Lambert obtained U.S. Patent No. 5,084,479 (the "'479 Patent"), claiming the use of gabapentin anhydrous to treat neurodegenerative diseases.[6] This patent expires on January 2, 2010.

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[5] Before this time, gabapentin was known to exist in two principal forms: (1) an anhydrous form where no water is associated with the gabapentin molecules and (2) a hydrated form where some water is associated with the gabapentin molecules. Only two hydrated forms were then known: (1) two gabapentin molecules associated with each molecule of water and (2) four gabapentin molecules associated with each molecule of water. Gabapentin monohydrate, by contrast, is very crystalline and can be purified to a high degree. After purification, the monohydrate form can be readily converted back to the anhydrous form, containing no water.

[6] The '479 Patent's dependent claims describe a method wherein the neurodegenerative disease is stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (A.L.S.), and Parkinson's disease. Warner-Lambert has neither sought nor received FDA approval to promote or market Neurontin for the treatment of neurodegenerative diseases.

At about the time Neurontin was approved by the FDA, Warner-Lambert amended its patent notification statement to include the '476 and '479 Patents, certifying that they also covered the formulation, composition and/or method of use of the drug product that was the subject of its NDAs. The '476 and '479 Patents were listed in the Orange Book in May 1994 and January 1996, respectively.

Warner-Lambert filed a final patent application, U.S. Patent Application No. 07/570,500 ("the '500 Application"), in August 1990. This patent covered the manufacturing process developed by the company to create a low-lactam form of gabapentin.[7] As described below, the parties dispute the details and objectives of the resulting patent prosecution. The low-lactam gabapentin patent was ultimately issued as U.S. Patent No. 6,054,482 (the "'482 Patent") on April 25, 2000 and it will expire on April 25, 2017.[8] Shortly after the '482 Patent issued, Warner-Lambert certified that it also covered the drug product at issue in both NDA No. 20-235 and NDA No. 20-882, resulting in an Orange Book listing for the '482 Patent as well.

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[7] Warner-Lambert scientists had discovered that under certain conditions during the manufacturing process, gabapentin has a tendency to form a lactam, which makes the drug unstable and unsafe. Warner-Lambert ultimately determined that all gabapentin products had to be essentially free from mineral acid impurities, and that certain adjuvants that promote the conversion of gabapentin to gabapentin lactam must be avoided. In an effort to minimize the formation of lactam during the manufacturing process, Warner Lambert developed the manufacturing process disclosed and claimed in this patent application.

[8] The '482 Patent discloses that gabapentin must be highly purified before being formulated into the pharmaceutical preparation. The patent also incorporates limits on the types of adjuvants (inactive ingredients) that can be used, since certain adjuvants reduce the stability of the drug. Accordingly, Claim 7 of the '482 Patent claims a "stable and pure pharmaceutical composition ... consisting essentially of" gabapentin containing "less than 0.5% by weight of its corresponding lactam" as well as "less than 20 ppm of an anion of a mineral acid," and "one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to ... lactam" when stored under certain conditions. U.S. Patent No. 6,054,482.

B. The Market For Neurontin

Warner-Lambert first began selling Neurontin capsules in early 1994. According to the FDA's required labeling, gabapentin is useful for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." This was the only use approved by the FDA prior to the launch of Neurontin.[9]

Once Warner-Lambert began marketing Neurontin however, doctors also began to use Neurontin to treat neurodegenerative conditions such as Parkinson's disease, A.L.S., and neuropathic pain, the uses covered by the '479 Patent but not approved by the FDA.[10] Increased awareness of Neurontin's off-label uses led to significant sales of the drug to treat conditions other than epilepsy. By 1998, Neurontin was being prescribed and used almost exclusively for off-label uses. *See* First Amended Complaint and Demand for Jury Trial of Plaintiffs CVS Pharmacy, Inc., Rite Aid Corporation and Rite Aid HDQTRS. Corp. ¶ 93, *In re Neurontin Antitrust Litig.*, No. 02-5583 (D.N.J. Feb. 14, 2008) ("Direct Purchaser Non-Class Complaint" or "DPNC Complaint").

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[9] Neurontin has subsequently been FDA-approved for the treatment of post-therapeutic neuralgia, a chronic debilitating pain frequently accompanying Shingles. Such use is not directly at issue in this proceeding.

[10] Under the Federal Food, Drug and Cosmetics Act ("FDCA"), pharmaceutical manufacturers may not market or promote a drug for a use that has not been approved by the FDA unless certain "stringent requirements" are met and the manufacturer resubmits the drug to the FDA testing and approval process. *United States ex re. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001). Once a drug is approved for a one use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such "off-label" usage is a widely-accepted practice that corresponds with the FDA's fundamental mission of regulating pharmaceuticals without interfering directly with the practice of medicine.

C. Abbreviated New Drug Applications And The Resulting Patent Infringement Litigation

Beginning in 1998, several generic drug manufacturers filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic gabapentin products after the expiration of the '544 patent (and its pediatric extension).[11] Purepac Pharmaceutical Co. ("Purepac"), the first generic applicant, filed two ANDAs: No. 75-370 for gabapentin capsules on March 30, 1998 and No. 75-694 for gabapentin tablets on September 3, 1999. When Purepac initially filed ANDAs, it submitted a Paragraph IV Certification concerning the '476 Patent and a section viii statement concerning the '479 Patent. Apotex Corp. ("Apotex") filed ANDA No. 75-360 for gabapentin capsules on April 17, 1998, and included a Paragraph IV Certification for both the '476 and '479 Patents. Similar ANDAs were subsequently filed by Geneva

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[11] In an ANDA, a generic manufacturer must make one of four certifications concerning each patent that is listed in the Orange Book in conjunction with the approved pioneer drug:

I. That no patent for the pioneer drug has been filed with the FDA (Paragraph I Certification);
II. That the patent for the pioneer drug has expired (Paragraph II Certification);
III. That the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (Paragraph III Certification); or
IV. That the patent for the pioneer drug is invalid or will not be infringed by the generic company's proposed product (Paragraph IV Certification).

21 U.S.C. § 355(j)(2)(A)(vii). Alternatively, an ANDA may assert that a patent is inapplicable to the indication for which the drug product will be marketed (a "section viii statement").

If a generic manufacturer files a Paragraph III Certification, the FDA will not approve the ANDA until the patent at issue expires. If a generic manufacturer chooses to file a Paragraph IV Certification, it must promptly disclose its Certification to both the NDA-owner and the patent-owner. Upon receipt of a Paragraph IV Certification, the patent-owner may initiate an action for patent infringement within 45 days, and if no such action is brought, the FDA may approve the generic manufacturer's ANDA. If an infringement action is brought within 45 days, FDA approval of the ANDA is automatically postponed for 30 months (unless a court issues a final decision that the patent is invalid or not infringed). 21 U.S.C. § 355(j)(5)(B)(iii).

Pharmaceuticals, Inc., Teva Pharmaceuticals USA, Zenith Goldline Pharmaceuticals, and Eon Labs Manufacturing, among others.

Based on these ANDA submissions, Warner-Lambert commenced patent infringement litigation against several generic applicants, alleging infringement of the '476 and '479 Patents.[12] In response, Purepac, Apotex and several other generic applicants asserted antitrust or unfair competition counterclaims similar to those pending before this Court in the instant action and in *In re Gabapentin Patent Litig*. By initiating infringement litigation, Warner-Lambert invoked the automatic 30-month stay provision, thereby requiring the FDA to stay approval of the generic manufacturers' ANDAs. Summary judgement of noninfringement was ultimately granted in favor of the generic applicants. *See, e.g.*, *Warner-Lambert Co. v. Purepac Pharm. Co., et al.*, Nos. 98-2749, 99-5948, 2003 WL 21698310 (D.N.J. May 22, 2003) (the "May 22 Opinion"). Plaintiffs now assert that these initial lawsuits were "objectively baseless and intended solely to illegally extend [Defendants'] monopoly by delaying the entrance of generic manufacturers into the gabapentin anhydrous market." DPNC Complaint ¶ 63.

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[12] Warner-Lambert filed, for example, two separate lawsuits in the United States District Court for the District of New Jersey against Purepac, one based on the ANDA for generic gabapentin capsules and the other based on the ANDA for generic gabapentin tablets. The "Capsule Lawsuit" was initiated in June 1998 (No. 98-2749) and the "Tablet Lawsuit" was initiated in December 1999 (No. 99-5948). In each lawsuit, Warner-Lambert asserted actual infringement of the '476 Patent and induced infringement of the '479 Patent. The lawsuits were consolidated for trial purposes in April 2001 in front of Hon. John C. Lifland, U.S.D.J.

Warner-Lambert filed a similar patent infringement action against Apotex in the United States District Court for the District of Illinois in July 1998. *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293 (N.D. Ill. filed July 14, 1998). Successive ANDA filings by other generic applicants led to the filing of subsequent infringement actions. *See, e.g, Pfizer Inc. v. Zenith Labs.*, No. 01-577 (D.N.J. filed Feb. 5, 2001); *Pfizer Inc. v. Pharm. Holding. Corp.*, No. 03-4017 (D.N.J. filed Feb. 5, 2003); *Pfizer Inc. v. Geneva Pharm., Inc.*, No. 03-1545 (D.N.J. filed Apr. 8, 2003).

Once the '482 Patent was issued and listed in the Orange Book, generic applicants amended their ANDAs to include Paragraph IV Certifications concerning that patent. The updated certifications led to another round of litigation, beginning in June 2000, as Warner-Lambert again filed multiple patent infringement actions against several generic manufacturers. These actions, asserting infringement of the '482 Patent, are those now pending before this Court in *In re Gabapentin Patent Litig.*[13]

Generic manufacturers began selling their gabapentin products "at risk" before a court ruling on infringement liability had issued. Purepac, for example, launched its gabapentin capsules in October 2004, and its gabapentin tablets in December 2004. Other manufacturers began selling generic gabapentin products in 2004 and 2005 as well.

II. Direct Purchaser Antitrust Actions

Plaintiffs in the instant action are direct purchasers of Neurontin.[14] Plaintiffs Louisiana Wholesale Drug Company ("Louisiana Wholesale"), Meijer, Inc., and Meijer Distribution, Inc.

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[13] A detailed and lengthy account of the procedural posture of the pending '482 Patent infringement actions is set forth in the Teva Opinion. Such information need not be reiterated in full for purposes of the instant motion, and is incorporated herein by reference.

[14] This proceeding originally involved actions filed by direct purchasers, individual consumers, insurers and others. Litigation was temporarily stayed on October 23, 2002, pending decisions in *In re Gabapentin Patent Litig.*, and was reactivated in February 2008 with the filing of amended complaints.

A Consolidated Class Action Complaint was filed by individual consumers and third-party payors (the "End Payors"), alleging violations of the antitrust and/or deceptive practices statutes of 22 states and the District of Columbia. The End Payors' Consolidated Complaint was dismissed on April 2, 2009, following the voluntary dismissal of each underlying individual End Payor action.

The instant motion pertains to the two remaining, active Amended Complaints, *Louisiana Wholesale Drug Co., Inc. v. Pfizer* (Nos. 02-1830, 02-2731) and *CVS Pharmacy, Inc. v. Pfizer* (No. 02-5583), each of which alleges various federal antitrust claims under Section 2 of the Sherman Act.

(collectively, "Meijer," and all collectively "Direct Purchaser Class Plaintiffs") filed an Amended Complaint asserting two counts of monopolization in violation of Section 2 of the Sherman Act.[15] The Direct Purchaser Class Plaintiffs bring this action on behalf of themselves and as representatives of a class of "[a]ll persons who directly purchased Neurontin from Defendant at any time during the period of July 16, 2000 until the effects of Defendant's conduct ceased." First Amended and Consolidated Class Action Complaint of Plaintiffs Louisiana Wholesale Drug Company, Inc., Meijer, Inc., and Meijer Distribution, Inc. ¶ 24, *In re Neurontin Antitrust Litig.*, Nos. 02-1830, 02-2731(D.N.J. Feb. 14, 2008) ("Direct Purchaser Class Complaint" or "DPC Complaint"). Excluded from the class are Defendants and their officers, directors, management and employees, predecessors, subsidiaries and affiliates, and all federal government entities.[16]

Plaintiffs CVS Pharmacy, Inc. (formerly CVS Meridian, Inc., "CVS"), Rite Aid Corporation, and Rite Aid HDQTRS. Corp. (collectively, "Rite Aid" and all collectively "Direct

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[15] Louisiana Wholesale, a Louisiana corporation, purchased Neurontin directly from Warner-Lambert. Meijer Distribution is a Michigan corporation and a wholly-owned subsidiary of Meijer, Inc., also a Michigan corporation. The Meijer Plaintiffs allege standing to assert federal antitrust claims as a direct purchaser of Neurontin by virtue of assignment to them of claims from Frank W. Kerr Co., which purchased Neurontin directly from Defendants during the class period.

[16] The Direct Purchaser Class Plaintiffs provide initial allegations in support of proceeding as a class action including: (1) that membership of the class is so numerous that joinder is impracticable; (2) that Plaintiffs' claims are typical, in that Plaintiffs and all class members were damaged by the same wrongful conduct; (3) that Plaintiffs will fairly and adequately protect and represent the interests of the class; (4) that Plaintiffs are represented by experienced and competent class counsel; (5) that common questions of law and fact predominate over those that may affect only individual class members because Defendants have acted on grounds generally applicable to the entire class; and (6) that class treatment is a superior method for the adjudication of this controversy and substantially outweighs any difficulties that may arise in management of this class action. DPC Complaint ¶¶ 25-31. The Court will address these issues, if necessary, upon a separate motion for class certification.

Purchaser Non-Class Plaintiffs") filed an Amended Complaint asserting one count of monopolization and one count of attempted monopolization, also in violation of Section 2 of the Sherman Act.[17] Plaintiffs in both actions seek similar relief, primarily a judgment that Warner-Lambert's actions are an unlawful restraint of trade in violation of the Sherman Act, treble damages for such actions, and reasonable costs and attorneys' fees. *See* DPC Complaint at 53; DPNC Complaint at 41.

Although the claims in each action are styled slightly differently, Plaintiffs have set forth virtually identical allegations concerning Warner-Lambert's anticompetitive conduct. Plaintiffs primarily allege that Warner-Lambert engaged in an "overall scheme" to monopolize the market for gabapentin anhydrous products by forestalling, if not completely preventing, generic competition for Neurontin.[18] Warner-Lambert is alleged to have carried out this scheme by:

> (1) procuring two additional patents that it improperly listed in the Orange Book; (2) manipulating the patent approval process so that a third patent with claims so limited that they are impossible to accurately measure or distinguish from the prior art so that the patent could be used to delay generic entry; (3) filing and prosecuting multiple sham

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[17] CVS, a Rhode Island corporation, purchases substantial quantities of pharmaceutical products and other goods for resale to the public through drugstores operated by affiliates. CVS purchased Neurontin from a range of wholesalers, who purchased the drug directly from Warner-Lambert. CVS is the assignee of its wholesalers' antitrust claims. Rite Aid, a Delaware corporation, also purchases substantial quantities of pharmaceutical products and other goods for resale to the public through drugstores operated by affiliates. Rite Aid purchased Neurontin from one wholesaler, McKesson, which purchased Neurontin directly from Warner-Lambert. Rite Aid is the assignee of McKesson's antitrust claims. Both CVS and Rite Aid bring this action in their own right and on behalf of the assignor wholesalers.

[18] The Direct Purchaser Class Plaintiffs also assert a separate count of monopolization based solely on Warner-Lambert's allegedly baseless patent infringement litigation. The allegations pled in support of this claim are identical to and subsumed within those pled in support of the "overall scheme" claim and do not, therefore, require separate analysis. This separate count will survive the instant motion to the same extent, and for the same reasons, that the allegations of sham litigation as part of an overall monopolization scheme survive.

> lawsuits on these patents that no reasonable litigant could have expected to succeed; and (4) engaging in fraudulent off-label promotion to convince doctors to prescribe Neurontin for uses for which it was not approved.

DPNC Complaint ¶ 29. Plaintiffs claim that these actions, taken together, foreclosed generic competition in the gabapentin anhydrous market and enabled Warner-Lambert to charge supracompetitive prices for Neurontin. As a result, consumers of gabapentin anhydrous were compelled to pay, and did pay, artificially inflated prices for the drug.

A. Allegations Of Patent Prosecution Misconduct

Specifically, Plaintiffs allege that Warner-Lambert manipulated the prosecution of the '482 Patent to provide additional protection for the Neurontin franchise and maximize the delay of generic competition through successive 30-month stays of generic approval. The filing of the initial '500 Application in 1990 led to a series of rejections by the patent examiner and continuation applications by Warner-Lambert. Continuation Application No. 08/020,270 (the "'270 Application"), filed in February 1993, was finally approved for issuance as U.S. Patent No. 5,395,852 (the "'852 Patent"). The '852 Patent was scheduled to issue on March 7, 1995.

Shortly before the issuance date, however, Warner-Lambert requested that the approved application be withdrawn in exchange for another continuation application, so that the patent examiner could consider the '476 Patent as well as U.S. Patent No. 4,152,326 (the "'326 Patent"), which is also directed to compounds related to gabapentin, assigned to Warner-Lambert and lists the same inventors. Plaintiffs now contend that Warner-Lambert knew about both patents and should have brought them to the examiner's attention far earlier in the prosecution process. They further allege that these delays were designed to provide Warner-Lambert with "the ability to time the eventual issuance of the patent to its greatest advantage." DPC Complaint

¶ 97; *see also* DPNC Complaint at 53-54. Warner-Lambert prosecuted its final continuation application over the next five years, allegedly stepping up its efforts only when it appeared that protection for Neurontin under other patents would soon expire.

The '482 Patent, as issued, has claims similar to those approved years earlier under the '270 Application, thereby implying, according to Plaintiffs, that Warner-Lambert could have patented the low-lactam formulation much earlier if the patent itself had been the company's actual objective. But this patent, Plaintiffs allege, was merely a "contingency" patent held in reserve for use in further delaying the launch of generic gabapentin.[19] Plaintiffs claim, in sum, that "Defendant intentionally delayed and prolonged the prosecution of its patent application in order to better use the patent ... to delay generic competition by improperly obtaining another automatic 30-month stay of FDA approval of generic ANDAs." DPC Complaint ¶ 99.

B. Allegations Of Improper Orange Book Listings

Plaintiffs further allege that Warner-Lambert submitted false and fraudulent information to the FDA in order to improperly list the '476 and '479 Patents in the Orange Book. They assert that Warner-Lambert listed these patents despite knowing that the patents "(1) did not claim an

[19] Plaintiffs further allege Warner-Lambert was hoping to use the delayed issuance of the '482 Patent to establish that patent as a "gap filler" between the originally expected expiration of Neurontin market exclusivity and the approval and launch of pregabalin, a successor drug to Neurontin. Warner-Lambert allegedly hoped to have pregabalin ready for launch prior to generic entry, so that it could shift consumers of Neurontin to pregabalin before losing those consumers to generic versions of Neurontin. Even with an accelerated timetable for the approval and launch of pregabalin, however, Warner-Lambert needed patent protection beyond that provided solely by the '175 and '544 Patents and allegedly used the '482 Patent to provide such protection. DPC Complaint ¶ 5; DPNC Complaint ¶ 30. Pregabalin was finally approved by the FDA in December 2004 for use in treating two forms of neuropathic pain. It is now sold as Lyrica.

approved drug or an approved method of using a drug, and (2) could not reasonably be asserted to be infringed upon by the sale of generic gabapentin anhydrous." DPNC Complaint ¶ 36. Warner-Lambert's certification concerning the '476 Patent was allegedly false and fraudulent because Warner-Lambert knew the '476 Patent claimed a different formulation or composition than the drug approved for sale as Neurontin. *Id.* ¶ 41. Plaintiffs contend that the certification concerning the '479 Patent was similarly false and fraudulent because that patent claimed only the use of gabapentin anhydrous to treat neurodegenerative disorders, not the FDA-approved use of Neurontin to treat epilepsy. *Id.* ¶ 43. Plaintiffs allege that Warner-Lambert listed these patents in the Orange Book "only so that it could take advantage of the ANDA approval process to delay generic approvals for up to 30 months." *Id.* ¶ 47.

Plaintiffs also challenge Warner-Lambert's subsequent listing of the '482 Patent. They allege that Warner-Lambert intentionally narrowed the patent claims covering the gabapentin substance, but nevertheless listed the '482 Patent in the Orange Book, certifying that it related to Neurontin and that infringement could be reasonably asserted against generic applicants. According to Plaintiffs, "this was improper ... because it is not possible to distinguish infringing from non-infringing generic products with regard to each claimed specification of the '482 patent and therefore the '482 patent should not have been listed in the Orange Book." DPC Complaint ¶ 101.

C. Allegations Of Sham Patent Litigation

Warner-Lambert's enforcement of the '476, '479, and '482 Patents through infringement litigation is also alleged to be a key component of the company's monopolization scheme. The initial lawsuits asserting the '476 and '479 Patents were, according to Plaintiffs, pursued without

either a reasonable basis or reasonable expectation for success, and were initiated "solely to illegally extend [Defendant's] monopoly by delaying the entrance of generic manufacturers into the gabapentin anhydrous market." DPNC Complaint ¶ 63.

The '476 Patent actions were allegedly baseless because the targeted ANDAs sought approval for a generic product using gabapentin anhydrous, not gabapentin monohydrate as claimed by the '476 Patent. Without an approved NDA for a drug containing gabapentin monohydrate, Plaintiffs allege that generic manufacturers were neither required nor permitted to file ANDAs for that substance.[20] The '479 Patent lawsuits were allegedly baseless because that patent claimed only a use of gabapentin that had not been approved by the FDA and for which the generic applicants were not seeking approval.[21] Plaintiffs thus contend that their generic products could not, therefore, infringe upon the '479 Patent. Without any real expectation of

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[20] Plaintiffs assert that Warner-Lambert's conduct during the '476 Patent actions further confirms that Defendants knew these lawsuits were neither objectively reasonable nor meritorious. Once the 30-month stay attributable to the various '476 Patent cases expired, and the lawsuits offered no further protection from generic competition under Hatch-Waxman, Warner-Lambert stopped pursuing the '476 Patent claims. Indeed, Warner-Lambert did not oppose summary judgment motions in the '476 infringement lawsuits, conceding that the generic products would not infringe that patent. *See* May 22 Opinion, 2003 WL 21698310.

[21] According to Plaintiffs, "Defendant's infringement complaints asserted that, since the '479 patent claimed *a* use of gabapentin (regardless of whether that use had passed muster with the FDA), any ANDA for generic Neurontin would be an act of infringement under this section, regardless of the fact that generic manufacturers would be unable to market gabapentin for the use claimed in the '479 patent." DPC Complaint ¶ 80.

The Federal Circuit ultimately rejected this theory, finding that it was "inconsistent with both the stated purposes of the Hatch Waxman Act, and would confer substantial additional rights on pioneer drug patent owners that Congress quite clearly did not intend to confer." *Warner-Lambert, Co. v. Apotex Corp.*, 316 F.3d 1348, 1359 (Fed. Cir. 2003). As a result, the Federal Circuit held that "because an ANDA may not seek approval for an unapproved or off-label use of a drug ... it necessarily follows that 35 U.S.C. 271(e)(2)(A) does not apply to a use patent claiming only such use." *Id*. at 1356.

success on the merits of these actions, "Defendant simply used these two patents to secure the 30-month stay of approval of generic ANDAs that is automatically triggered by the filing of an infringement suit regarding an Orange Book-listed patent." DPC Complaint ¶ 7.

Plaintiffs similarly allege that the litigation concerning the '482 Patent is baseless and likewise intended to further delay the approval and launch of generic products. Plaintiffs assert that because the claims of the '482 Patent are formulated so narrowly, it is not possible to determine whether generic products would actually infringe that patent.[22] According to Plaintiffs, Warner-Lambert was well aware of this fact yet still initiated infringement actions. "A reasonable litigant," however, "would have realized that the inability of technology to quantify and distinguish the level of chloride ions at the low levels specified by the '482 patent would make it objectively impossible to succeed on the litigation based on infringement of the '482 patent." DPC Complaint ¶ 106.[23]

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[22] Plaintiffs allege that there are no analytical tests at this time to sufficiently or accurately differentiate the 20 ppm chloride ions from the 22 ppm chloride ions covered by prior patents. DPC Complaint ¶ 105.

[23] Plaintiffs support many of the allegations just described by referring to certain internal marketing documents created and maintained by Warner-Lambert. According to Plaintiffs, despite the existence, listing and litigation of the '476, '479, and '482 Patents, Warner-Lambert was still predicting generic competition for Neurontin in 2000, when the '544 Patent expired, rather than when the other patents expired years later. Other internal documents indicate that Warner-Lambert chose not to seek FDA approval for additional indications because there was not enough time to do so before the expiration of the patents that Warner-Lambert believed were protecting the market.

Plaintiffs allege that these documents establish that Warner-Lambert "recognized that these patents provided no genuine exclusionary force because Defendant could not use these patents to obtain a court order enjoining generic competition." DPC Complaint ¶ 7. If Warner-Lambert believed that the '476 and '479 Patents, for example, were actually "capable of providing patent protection by covering an approved drug or use, as required for listing in the Orange Book [and subsequent patent infringement litigation] then Defendant would have been projecting internally that Neurontin had patent protection through at least 2008 (or 2010), and

D. Allegations Of Off-Label Marketing

Finally, Plaintiffs allege that Warner-Lambert, having recognized that potential lifetime sales of Neurontin would be limited, also attempted to unlawfully maintain its monopoly over the gabapentin anhydrous market by fraudulently promoting the drug for off-label uses.[24] Rather than facing this challenge in a lawful manner or developing legitimate alternative profit streams, Warner-Lambert allegedly decided to aggressively and illegally promote Neurontin for a variety of off-label uses without seeking additional FDA approval.[25] "Defendant's purpose in pursuing

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would have developed its plans and strategies in reliance upon that protection." *Id*. at 50. Plaintiffs present similar allegations about the '482 Patent and Warner-Lambert's recognition that it would protect the Neurontin franchise only for the duration of the automatic 30-month-stay. *Id*. at 102. These documents, Plaintiffs allege, confirm the anticompetitive nature of any actions taken by Warner-Lambert with respect to these patents. Defendants dispute the conclusions drawn by Plaintiffs.

[24] Plaintiffs allege that Defendants conceived their monopolization scheme upon realizing that there were significant regulatory limits to their ability to generate sufficient revenues and profits from Neurontin: "First, Defendant recognized that its ability to legally market Neurontin was limited, since it had only received FDA approval for a single indication, as an adjunctive therapy for epilepsy. Second, Defendant recognized that it had just six years during which Neurontin would be free from generic competition." DPNC Complaint ¶ 27. Defendants allegedly attempted to respond to this situation by unlawfully expanding the market and delaying entry of generic competitors.

[25] The Direct Purchaser Plaintiffs are not the first to challenge Warner-Lambert's marketing of Neurontin. The Department of Justice investigated Warner-Lambert's marketing conduct over a seven-year period, filing felony criminal charges in the District of Massachusetts on May 13, 2004. Warner-Lambert was charged with the criminal distribution of an unapproved new drug and distribution of a misbranded drug. Warner-Lambert ultimately admitted that its marketing of Neurontin was criminal, pled guilty to the charges on June 7, 2004, and agreed to pay more than $430 million in sanctions, along with restitution to federally-funded Medicaid programs.

Consumer purchasers and third-party payors also brought suit against Warner-Lambert for violations of the Racketeer Influenced and Corrupt Organizations Act (RICO) and the New Jersey Consumer Fraud Act (NJCFA), alleging that Warner-Lambert engaged in a fraudulent scheme to promote and sell the drug Neurontin for "off-label" conditions. That proceeding is currently pending before Hon. Patti B. Saris, U.S.D.J., in the District of Massachusetts. *In re:*

the illegal promotion campaign" was, Plaintiffs assert, "to quickly and dramatically grow the market for Neurontin in the years prior to anticipated loss of market exclusivity." DPC Complaint ¶ 67. By publishing misleading articles, withholding studies showing that Neurontin was not effective for certain off-label uses, and encouraging salespeople to use biased "medical liaisons" in sales pitches to physicians, among other tactics, Warner-Lambert allegedly hoped to induce prescription of Neurontin for unapproved uses. This would then inflate Warner-Lambert's market share and profits without having to satisfy the FDA's rigorous requirements for approving additional indications for Neurontin. Plaintiffs claim that Warner-Lambert's off-label marketing campaign directly affected the market for gabapentin anhydrous and must, therefore, be considered as integral to the company's overall monopolization scheme.

III. Legal Standards

A. Motion To Dismiss

On April 1, 2008, Defendants filed a consolidated motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), seeking to dismiss all of the federal antitrust claims asserted by the Direct Purchaser Plaintiffs. To survive a motion to dismiss filed under Rule 12(b)(6), "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true," even if doubtful in fact. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007) ("*Twombly*"). According to the Third Circuit, "stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead

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Neurontin Marketing, Sales Practices and Products Liability Litig. No. 04-10981, MDL No. 1629; *see also In re Neurontin Marketing, Sales Practices and Products Liability Litig.*, 618 F. Supp. 2d 96 (2009) (outlining history of and claims asserted in the civil multi-district litigation).

simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (internal quotations omitted) (citing *Twombly*, 550 U.S. at 555-56).

Although a court does not need to credit a complaint's "bald assertions" or "legal conclusions," it must view all of the allegations in the complaint as well as all reasonable inferences that can be drawn therefrom in the light most favorable to the plaintiff. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (citing *Rocks v. City of Philadelphia*, 868 F.2d 644, 645 (3d Cir. 1989)); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429-30 (3d Cir. 1997). The Supreme Court recently held that "once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 546.[26]

Antitrust complaints, in particular, are to be liberally construed at this stage of the proceeding. *See In re Hypodermic Prods. Antitrust Litig.*, MDL No. 1730, 2007 WL 1959224, at *5 (D.N.J. June 29, 2007) (citing *Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988)). "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators,' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hosp. Building Co. v. Trustees of Rex Hosp.*, 425 U.S. 738 (1976) (quoting *Poller v. Colombia Broad.*, 368 U.S. 464, 473 (1962)). "The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the

[26] In evaluating a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court may consider only the allegations pled in the complaint, exhibits attached to the complaint, matters of public record, and undisputedly authentic documents if a plaintiff's claims are based on those documents. *Pension Ben. Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1992).

fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *See Lucas Indus. v. Kendiesel, Inc.*, No. 93-4480, 1995 WL 350050, at *2 (D.N.J. June 9, 1995). Nevertheless, courts have determined that "the heavy costs of modern federal litigation, especially antitrust litigation, and the mounting caseload pressure on the federal courts," militate in favor of requiring some reasonable particularity in pleading violations of the federal antitrust laws. *See Sutliff, Inc. v. Donovan, Co.*, 727 F.2d 648, 654 (7th Cir. 1984); *Garshman v. Universal Res. Holding, Inc.*, 641 F.Supp. 1359, 1367 (D.N.J. 1986).

B. Antitrust Claims

The purpose of the Sherman Act is "to protect the public from the failure of the market." 15 U.S.C.A. § 2 n.5 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447 (1993)). The Direct Purchaser Plaintiffs have asserted claims of monopolization and attempted monopolization under Section 2 of the Sherman Act, which provides in pertinent part that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony." 15 U.S.C. § 2. Section 16 of the Clayton Act allows a person "threatened [with] loss or damage by a violation of the antitrust laws" to seek injunctive relief. The Clayton Act includes the Sherman Act as one of the applicable "antitrust laws."

A claim for monopolization has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or

historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).[27] A monopolization claim does not require proof of the specific intent to monopolize, demanding only proof of "a general intent to do the act, for no monopolist monopolizes unconscious of what he is doing." *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 626 (1953) (internal quotations and citations omitted). Nevertheless, "the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). This requirement is particularly important in the patent context, because patents inherently grant certain rights to exclude competition. Actions that are permissible under the patent laws, such as the mere maintenance of the statutory patent monopoly, cannot therefore give rise to antitrust liability. *See, e.g.*, *Hoffman-La Roche Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 378 (D.N.J. 1999); *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at *2-3 (E.D. Pa. July 18, 2000).[28]

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[27] Monopoly power is defined as "the power to control prices or to exclude competition." *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 111-12 (3d Cir. 1992).

[28] As one court observed, "[t]he presence of a patent informs our entire analysis here, because patent laws and antitrust laws exist in tension, as the patent laws protect monopoly power while antitrust laws seek to restrain it. ... Thus, any allegation of antitrust resulting from a patent must extend beyond the rights granted in the patent, and conduct permissible under the patent laws cannot trigger antitrust liability." *Sheet Metal Duct, Inc.*, 2000 WL 987865, at *2 (internal quotations and citations omitted).

However, patent holders can violate antitrust laws if they seek to expand the limited monopoly granted by their patents. *See, e.g.*, *DiscoVision Assoc. v. Disc Mfg., Inc.*, Nos. 95-21 & 95-345, 1997 WL 309499, at *8 (D. Del. Apr. 3, 1997) (citing *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981)). "[A]ntitrust liability under section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998), *cert. denied*, 526 U.S. 1130 (1999). In addition, a claim may be stated for violation of Section 2

A claim for attempted monopolization has three elements: (1) predatory or exclusionary conduct; (2) the possession of the specific intent to monopolize; and (3) a dangerous probability of achieving monopoly power or succeeding in the attempt to monopolize. *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 750 (3d Cir. 1996) (citing *Spectrum Sports,* 506 U.S. at 454-58). "Whether a party violates § 2 of the Sherman Act by attempting to monopolize is a question of proximity and degree." *Id*. (citations omitted). To determine whether there is a "dangerous probability of monopolization," courts will consider "the relevant market and the defendant's ability to lessen or destroy competition in that market." *Spectrum Sports*, 506 U.S. at 456.[29]

IV. Discussion

Warner-Lambert seeks dismissal of both the Direct Purchaser Class Complaint and the Direct Purchaser Non-Class Complaint for failure to state a claim. According to Warner-Lambert, Plaintiffs' claims are simply an attempt to reargue that Warner-Lambert's Orange Book listings and gabapentin patent infringement lawsuits were baseless, even though "these issues

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if the patentee brings an infringement suit as "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) ("*Noerr*"). Antitrust claims may also be based on allegations of manipulation of the Hatch-Waxman regulatory framework. *See, e.g.*, *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) ("*Teva Pharmaceuticals*"); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D.N.J. 2004) ("*Remeron*").

[29] "[A]lthough the size of a defendant's market share is a significant determinant of whether a defendant has a dangerous probability of successfully monopolizing the relevant market, it is not exclusive." *Barr Labs.,* 978 F.2d at 112. "Other factors to be considered include the strength of the competition, probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct, and the elasticity of consumer demand." *Id*.; *see also Crossroads Cogeneration Corp. v. Orange & Rockland Util., Inc.*, 159 F.3d 129, 141 (3d Cir. 1998).

have been evaluated favorably to [Warner-Lambert] by the courts during 10 years of patent litigation." Memorandum in Support of Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Claims at 2, *In re Neurontin Antitrust Litig.*, No. 02-1390 (D.N.J. Apr. 1, 2008) ("Defendants' Opening Brief"). Furthermore, "[P]laintiffs' claims are foreclosed by their failure to satisfy fundamental antitrust requirements concerning competitive impact, antitrust injury, causation and the four-year statute of limitations." *Id*.

In response, Plaintiffs emphasize the sufficiency of their Amended Complaints. They argue that they have more than adequately pled cognizable violations of Section 2 of the Sherman Act, and that such violations are not immunized by the *Noerr-Pennington* doctrine. They also challenge Warner-Lambert's attempts to use certain opinions in the related patent infringement lawsuits to validate the company's actions, because those opinions are not binding in this litigation and should not, Plaintiffs argue, even be considered by this Court.

The instant motion challenges the Direct Purchaser Complaints on both substantive and procedural grounds. For the sake of clarity, the Court will first address Warner-Lambert's procedural grounds for dismissal and then turn to Defendants' substantive arguments for dismissal.

A. Statute Of Limitations

Warner-Lambert argues that Plaintiffs' claims based on the delayed prosecution of the '482 Patent and the off-label marketing of Neurontin should be dismissed because they are barred by the relevant statute of limitations. An antitrust cause of action has a 4-year limitations period, plus any additional number of years during which the statute of limitations was tolled, and

generally accrues "when a defendant commits an act that injures" the plaintiff. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 338 (1971).

Warner-Lambert asserts that any antitrust action based on the prosecution of the '482 Patent accrued, at the latest, on July 20, 2000, when Warner-Lambert sued Purepac and Apotex for infringing the '482 Patent and thereby imposed an additional 30-month stay of generic approval. Any claims concerning Warner-Lambert's off-label marketing activities accrued, according to Defendants, in 1995, when Warner-Lambert executives allegedly implemented their plans for off-label promotional efforts. Warner-Lambert argues that these actions all occurred more than four years prior to the date on which the Direct Purchaser Plaintiffs' Complaints were filed, and are, therefore, beyond the applicable statute of limitations.

Plaintiffs respond that their claims survive because they were timely filed and that any new allegations in the Amended Complaints relate back to those pled originally. The first complaint in the consolidated antitrust action was filed on March 26, 2002, and it alleged monopolization in the market for gabapentin anhydrous as well as the baselessness of the infringement actions concerning the '476, '479, and '482 Patents. The Amended Complaints that now control this proceeding were filed on February 14, 2008 pursuant to a schedule set by the Court. While these Complaints include additional factual allegations based on information obtained by Plaintiffs through discovery in the related patent proceedings or information that has come to light in the intervening years, particularly with respect to Warner-Lambert's off-label marketing efforts, such allegations are pled in support of the same monopolization claims asserted originally. These allegations are not now presented as the basis for additional,

independent causes of action. These allegations thus relate back, within the meaning of Fed. R. Civ. P. 15(c)(1)(B), to those in the original complaints.[30]

Furthermore, the Court notes that this proceeding was stayed by an Order of Hon. John Lifland, U.S.D.J., from October 31, 2002 until early 2008, and the intervening years do not impact the statute of limitations period. *See DiPippa v. United States*, 687 F.2d 14, 20 (3d Cir. 1982) (recommending that the district court stay proceedings pending the resolution of related matters in order to "avoid statute of limitations problems"); *Baglione v. Clara Maass Med. Center, Inc.*, No. 99-4069, 2006 WL 2591119, at *3 (D.N.J. Sept. 8, 2006) (noting that "a stay of proceedings ... would have tolled the statute of limitations and avoided any statute of limitations problems."). Accordingly, this Court finds that the Direct Purchaser Plaintiffs' antitrust claims,

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[30] Rule 15(c)(1)(B) provides in pertinent part that an amendment relates back to the date of the original pleading when "the amendment states a claim or defense that arose out of the conduct, transaction or occurrence set out - or attempted to be set out - in the original pleading."

Specifically, Warner-Lambert argues that any new allegations concerning the prosecution of the '482 Patent do not relate back to those originally pled because they do not arise out of the same "conduct, transaction or occurrence." *See Mayle v. Felix*, 545 U.S. 644, 659 (2005) (holding that "relation back depends on the existence of a common 'core of operative facts' uniting the original and newly asserted claims."). Defendants claim that the new allegations differ in time from the original allegations "because the entire prosecution of the '482 Patent necessarily occurred before the patent issued, while the listing and subsequent infringement actions necessarily occurred afterwards." Reply Memorandum in Support of Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Claims at 28, *In re Neurontin Antitrust Litig.*, No. 02-1390 (D.N.J. June 5, 2008) ("Defendants' Reply Brief"). They also claim that the new allegations differ in type because they "implicate Patent Office regulations regarding continuing applications whereas the original claims involved FDA listing regulations and whether the generics infringed the patent claims." *Id.*

These arguments are unpersuasive. All of Plaintiffs' allegations concerning the '482 Patent arise out of the alleged overarching monopolization scheme, and can, therefore, be considered part of the same overall "conduct, transaction or occurrence." Similarly, Plaintiffs' allegations of off-label promotion also relate back to the original allegations of Warner-Lambert's overall monopolization scheme and are pled in support of the same causes of action.

as pled in the currently-operative Amended Complaints, are not barred by the applicable statute of limitations.

B. Antitrust Injury

Warner-Lambert also argues that Plaintiffs' antitrust claims based on '476 and '479 Patent infringement lawsuits as well as those based on the off-label marketing of Neurontin should be dismissed because Plaintiffs did not suffer an antitrust injury from these actions. Antitrust plaintiffs must establish standing to pursue their claims. A threshold requirement for antitrust standing is proof of "antitrust injury," which requires that the injury be "causally linked to an illegal presence in the market." *Brunswick v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). To this end, a plaintiff must show both harm of the type the antitrust laws were intended to prevent, and an injury to the plaintiff which flows from that which makes the defendant's actions unlawful. *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*, 995 F.2d 425, 429 (3d Cir. 1993). Once an antitrust injury has been established, the plaintiff must further establish that he or she is a proper antitrust plaintiff.[31]

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[31] Antitrust standing requirements insure that litigants will use the antitrust laws to prevent anticompetitive actions and to deal only with the economic problems whose solutions those laws were specifically intended to effect. To determine whether a plaintiff has standing to pursue antitrust claims, courts consider the following:

> (1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm; (2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall; (3) the directness or indirectness of the asserted injury; (4) whether the claim rests on some abstract or speculative measure of harm; and (5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

Warner-Lambert Co. v. Purepac Pharm. Co., Nos. 98-2749, 99-5948, 00-2053, 2000 WL 34213890, at *7-8 (D.N.J. Dec. 22, 2000) (the "December 22 Opinion"); *see also Indium Corp.*

Warner-Lambert's arguments that Plaintiffs have failed to plead antitrust injury focus on the second element of the *Gulfstream* standard and are essentially causation arguments. Defendants contend that Plaintiffs' claims should be dismissed because Plaintiffs fail to allege antitrust injury specifically flowing from the '476 and '479 infringement actions or the off-label promotion of Neurontin. Warner-Lambert argues that: (1) Plaintiffs' allegations concerning the patent litigation cannot support antitrust claims because generic competition was impossible regardless of the 30-month stay imposed by the '476 and '479 patent actions;[32] and (2) that the inability of generic manufacturers to obtain even tentative FDA approval until after the stays associated with the '476 and '479 Patent suits expired was an independent barrier to generic entry.[33]

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of America v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed. Cir. 1985) (quoting *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 534-45 (1983)); *St. Clair v. Citizens Fin. Group*, No. 08-1257, 2008 WL 4911870, at *4 (D.N.J. 2008) (same).

Nevertheless, there is no black-letter rule for determining standing in every antitrust case. *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 922 (3d Cir. 1999) (observing that "[t]he [Supreme] Court has emphasized that lower courts should avoid applying bright-line rules and instead should analyze the circumstance of each case, focusing on certain key factors.").

[32] According to Warner-Lambert, the '544 Patent term began before and the '482 Patent 30-month stay ended after the stays associated with the '476 and '479 Patents and, therefore, foreclosed generic entry into the market regardless of the '476 and '479 lawsuits.

[33] An ANDA applicant cannot receive final FDA approval during the 30-month stay period. Nevertheless, the FDA grants "tentative approval" when it determines that the ANDA has satisfied the FDA's non-patent regulatory requirements and would receive final approval but for the 30-month stay. 21 C.F.R. §§ 314.105(a); 314.107(b)(3)(v). Warner-Lambert emphasizes that Purepac, the first generic filer (and therefore entitled to an 180-day period of generic exclusivity) did not meet the FDA requirements for approval until April 25, 2002, four months after the stays caused by the '476 and '479 Patents had expired.

Similarly, Warner-Lambert contends that Plaintiffs cannot show an antitrust injury from any off-label marketing of Neurontin because the alleged injury is not connected to an antitrust violation. "All the alleged off-label marketing could have done," Defendants argue, "was enhance competition between Neurontin® and alternative drugs in some undefined, unpleaded relevant market. This does not meet the requirement that injury must flow from that which would make the alleged conduct an antitrust violation." Defendants' Opening Brief at 6.[34]

Proving antitrust injury depends, at least in part, on establishing a causal link to an antitrust violation. *See Brunswick*, 429 U.S. at 489. Warner-Lambert's arguments are, in essence, that Plaintiffs cannot prove that such a causal link exists in this case. Such arguments do not, however, require the dismissal of Plaintiffs' claims at this stage of the litigation.

First, the Court notes that "the existence of antitrust injury is not typically resolved through motions to dismiss." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (citing *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995)); *see also In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (denying motion to dismiss antitrust claims on similar grounds because "Plaintiffs may be able to prove that the allegedly frivolous lawsuits 'materially caused' their alleged injuries.")

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[34] According to Warner-Lambert, any off-label promotion was designed to convince purchasers to buy Neurontin rather the competing drugs that would have otherwise been used to treat the conditions addressed by Neurontin's off-label uses. The impact of such conduct would, therefore, have occurred in the market for such other drugs. Defendants claim that, as a result, Plaintiffs cannot show that the off-label marketing contributed to market power or created anticompetitive results in the market for gabapentin anhydrous, such that this conduct is not actionable under Section 2. *See, e.g.*, *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 205-06 (3d Cir. 1992) (holding that where a defendant is alleged to have leveraged monopoly power in one market to affect competition in a second market, that conduct cannot form the basis for a Section 2 claim unless the defendant also has market power in the second market).

("*Wellbutrin*"); *Zenith Radio Corp.*, 395 U.S. at 114 n.9 (noting that an antitrust plaintiff may establish antitrust injury with "proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage.").

Second, in arguing that none of its alleged anticompetitive activities proximately caused the delayed launch of generic products, Warner-Lambert compartmentalizes or fragments Plaintiffs' allegations concerning an overall monopolization scheme. The Direct Purchaser Plaintiffs need not allege proximate cause or antitrust injury separately for each component of the alleged scheme. The injuries arguably inflicted by Warner-Lambert's allegedly anticompetitive activities should, instead, be viewed as a whole. *Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d 750, 767 (D.N.J. 1999) ("Again, this court will not evaluate whether each and every anticompetitive act upon which Biovail's antitrust claims are based directly caused Biovail injury. Instead, it will determine whether Biovail was injured by the anticompetitive conduct as a whole, an analysis the court will refrain from conducting until it is established that an antitrust violation has been pleaded."); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (same); *Teva Pharmaceuticals*, 432 F. Supp. 2d at 430-31.

Similarly, Plaintiffs need not allege that Warner-Lambert's anticompetitive actions were the sole cause of its injury. *See Zenith Radio Corp.*, 395 U.S. at 114 n.9 ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury."); *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 401 (7th Cir. 1993) ("An antitrust violation need not be the sole cause of the alleged injuries, but the plaintiff must establish, with a fair degree of certainty, that the violation was a material element of, and substantial factor in producing, the injury."). Plaintiffs need not "allege

(or dispose of) all alternative theories of causation to survive a motion to dismiss." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004). Rather, they are "simply required to allege facts showing that [they] suffered the type of injury or harm the antitrust laws were intended to prevent, and that [their] injury flows from[Warner-Lambert's] anti-competitive conduct." *Id*.

Nor are Plaintiffs required at this stage of the proceeding to adduce proofs discrediting all possible intervening causes of the delayed launch of generic products, such as the failure to obtain tentative generic approval from the FDA before the expiration of the 30-month stays at issue. Several courts have held that a finding of antitrust injury cannot be tied to the status of FDA approval of a generic applicant. *See Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 544-46 (D.N.J. 2000) (accepting the counterclaimants' contention that they need not demonstrate FDA approval in order to invoke antitrust standing). In *Abbott Laboratories. v. Mylan Pharmaceuticals., Inc.*, for example, the court observed that basing antitrust injury on "the status of FDA approval relative to the required timing of the suit" would render such injury "wholly contingent on the vagaries of timing of agency action." No. 05-6561, 2007 WL 625496, at *4 n.2 (N.D. Ill. Feb. 23, 2007) (internal quotations and citations omitted) ("*Mylan*").

The Direct Purchaser Plaintiffs have alleged that Warner-Lambert manipulated the regulatory advantages afforded by its gabapentin patents in order to prevent the entry of generic competitors into the Neurontin market and thereby unlawfully maintain a monopoly over that market. Neurontin purchasers were, as a result, forced to pay higher prices. According to Plaintiffs, Warner-Lambert "overcharged Plaintiffs and other direct purchasers of Neurontin hundreds of millions of dollars by depriving them of the benefits of competition from cheaper

generic versions of Neurontin." DPC Complaint ¶ 16. Plaintiffs further allege that Warner-Lambert's off-label promotion of Neurontin built up the market in which the company then proceeded to charge such prices, and that such activities should be considered when evaluating the injuries inflicted by Warner-Lambert's monopolization scheme as a whole. Moreover, Plaintiffs claim that absent Warner-Lambert's overarching scheme, generic manufacturers would have launched their products and purchasers would have had access to lower-priced drugs years earlier then they ultimately did.[35]

Courts have regularly held that such conduct creates the anticompetitive effect that the antitrust laws were designed to prevent, and therefore constitutes antitrust injury. *See, e.g.*, *Mylan*, 2007 WL 625496, at *4-5 (holding that Defendant Mylan established antitrust injury and standing by alleging that Plaintiff Abbott Labs used "the regulatory advantage afforded via a fraudulently-procured patent to prevent Mylan's entrance into the relevant market" and that Mylan had been ready to enter the market "but for Abbott's actions in fraudulently procuring the patents."); *Teva Pharmaceuticals*, 432 F. Supp. 2d at 431 (finding antitrust injury on the basis of allegations that Teva was excluded from a market while patent litigation remained unresolved because "[s]uch exclusion from the market is 'precisely the type of injury that the antitrust laws were intended to prevent,' because it reflects an injury to competition.") (internal citations omitted);[36] *see also In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 534 ("Specifically, Plaintiffs

[35] While Plaintiffs may have difficulty providing that generic manufacturers would have been able to launch their products earlier than they did, that is an issue most appropriately addressed at the summary judgment stage of the proceeding.

[36] Indeed, the Court notes that Judge Lifland reached a similar conclusion in the related gabapentin patent litigation, holding that Purepac had standing to pursue antitrust counterclaims on the basis of similar allegations of antitrust injury. In his December 22 Opinion, Judge Lifland

have alleged that these agreements caused them to pay higher prices for K-Dur, the type of injury the antitrust laws are intended to prevent. Plaintiffs are not required to plead more."); *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000) (observing that where a brand manufacturer "attempt[ed] to prevent and/or delay [FDA] approval" of competing generics, "[i]t is difficult to imagine a more formidable demonstration of antitrust injury.").

Accordingly, this Court finds that the Direct Purchaser Plaintiffs have sufficiently alleged that they have suffered an antitrust injury in the form of overcharges on their purchases of gabapentin anhydrous and that such injuries flowed from Warner-Lambert's allegedly unlawful conduct. When evaluated as a whole, the Court need not determine whether each element of Warner-Lambert's alleged monopolization scheme imposed its own antitrust injury. Warner-Lambert's motion to dismiss Plaintiffs' claims based on '476 and '479 Patent infringement lawsuits and the off-label marketing of Neurontin for failure to allege antitrust injury is, therefore, denied.

C. "Overall Scheme" Claim

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held that Warner-Lambert filed patent infringement actions against Purepac and, in doing so, delayed FDA approval of Purepac's ANDAs. December 22 Opinion, 2000 WL 34213890, at *8. Because the decision to initiate litigation was made by Warner-Lambert, rather than the FDA, Judge Lifland found the decision to be a purposeful exercise of power under Hatch-Waxman regulations "to temporarily foreclose Purepac's access to the market for gabapentin," as Purepac had alleged. *Id.* As a result, Judge Lifland held that Purepac had sufficiently alleged a causal connection between Warner-Lambert's actions and Purepac's injury and therefore had standing to pursue its antitrust counterclaims.

Plaintiffs in this action have cited Judge Lifland's opinions in further support of their position. While the previous decision is not controlling, as it is for certain issues still pending in the related patent proceedings, the Court notes that Judge Lifland's analysis is nonetheless persuasive.

The Direct Purchaser Plaintiffs allege that Warner-Lambert "willfully and unlawfully maintained its monopoly power by engaging in an overarching scheme to exclude competition that discouraged rather than encouraged competition on the merits." DPC Complaint ¶ 133. This scheme was allegedly designed for the anticompetitive purpose of forestalling generic competition and allegedly carried out with the anticompetitive effect of maintaining supracompetitive prices for gabapentin anhydrous products. Although Plaintiffs claim that Warner-Lambert implemented its scheme by improperly listing patents in the Orange Book, manipulating the prosecution of the '482 Patent, prosecuting multiple sham patent infringement lawsuits, and fraudulently and unlawfully marketing Neurontin for off-label uses, they are not, for the most part, asserting independent antitrust violations on the basis of these predicate actions. Rather, Plaintiffs repeatedly challenge Warner-Lambert's overall pattern of alleged abuse of its gabapentin patents and the patent regulatory process itself, emphasizing that this Court "may, and should, properly consider the entirety of Defendant's illegal and exclusionary conduct when assessing the anticompetitive impact of Defendant's scheme on competition in the market for gabapentin anhydrous." Revised Joint Memorandum of Direct Purchaser Plaintiffs in Opposition to Defendants' Motion to Dismiss Their Complaint at 25, *In re Neurontin Antitrust Litig.*, No. 02-1390 (D.N.J. May 16, 2008) ("Plaintiffs' Opposition Brief").

Warner-Lambert moves to dismiss Plaintiffs' overarching scheme claim because none of the specific conduct alleged by Plaintiffs is independently actionable under federal antitrust laws. Plaintiffs cannot, according to Warner-Lambert, rely on "everything together" to "independently create a basis for suit when ... each thing separately fails to state a claim." Defendants' Opening Brief at 6. Furthermore, courts that have previously allowed antitrust plaintiffs to pursue "overall

scheme" claims have only done so because the alleged scheme included exclusionary conduct that was itself unlawful.[37] Warner-Lambert argues that none of its underlying conduct violates antitrust laws, and therefore a scheme claim must fail because "[a]ggregating lawful conduct does not state a claim." Defendants' Reply Brief at 5.

In support of this argument, Defendants rely heavily on *Intergraph Corp. v. Intel Corp.* in which a manufacturer of graphics workstations asserted several theories of antitrust liability against the manufacturer of the microprocessors used in such workstations. On appeal, Intergraph argued "that the various theories of antitrust liability discussed by the district court should not be viewed separately but should be taken together, lest the slate be 'wiped clean' after each aspect fails to violate the Sherman Act." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1366 (Fed. Cir. 1999). The court rejected this argument, holding that the "proper analytical approach" is to analyze various theories "individually" even if "many of the issues ... are interrelated and independent." *Id*. at 1367. Warner-Lambert argues that this case holds that if none of the alleged conduct could support an antitrust claim on its own, either because it was not harmful to competition or was permitted by the patent laws, then the conduct cannot amount to an antitrust violation if "taken together." *See also City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) ("Each legal theory must be examined for its sufficiency and applicability, on the entirety of the relevant facts."); *Ne. Tel. Co. v. AT&T Co.*, 651 F.2d 76,

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[37] Warner-Lambert explains that the plaintiffs in *Remeron*, for example, alleged the improper listing of a patent that the court found could, itself, form the basis of an antitrust claim. 335 F. Supp. 2d at 532. Similarly, *Continenal Ore Co. v. Union Carbide & Carbon Corp.* involved an illegal group boycott, and the court assumed that "the respondents committed the alleged violations of the Sherman Act" through "specific acts ... performed as part of the basic plan to monopolize the vanadium market." 370 U.S. 690, 698-99 (1962) ("*Continental Ore*").

95 n.28 (2d Cir. 1981) (where anticompetitive conduct claims are individually shown "in numerous critical respects [to be] utterly lacking" they "collectively cannot have any synergistic effect" rescuing their validity).

Warner-Lambert also cites *Pacific Bell Telelphone Co. v. Linkline Communications, Inc.*, ("*Linkline*"), a case recently decided by the United States Supreme Court. In *Linkline*, the Court evaluated a price-squeeze claim brought by Internet Service Providers ("ISPs") who sold digital subscriber line ("DSL") access to internet to retail customers. Plaintiffs argued that the telephone companies that owned the infrastructure and facilities required to provide DSL service monopolized and attempted to monopolize the regional DSL market by charging high wholesale prices to the ISPs for DSL transport and low retail prices to consumers for DSL Internet service, thereby squeezing the profits earned by the ISPs. The Court rejected this claim, finding that the ISPs stated neither a duty-to-deal claim at the wholesale level nor a predatory pricing claim at the retail level. *Linkline*, 129 S. Ct. 1109, 1120 (Feb. 25, 2009). Specifically, the Court held that:

> In this case, plaintiffs have not stated a duty-to-deal claim under *Trinko* and have not stated a predatory pricing claim under *Brooke Group*. They have nonetheless tried to join a wholesale claim that cannot succeed with a retail claim that cannot succeed, and alchemize them into a new form of antitrust liability never before recognized by this Court. We decline the invitation to recognize such claims. Two wrong claims do not make one that is right.

Id. at 1123. Warner-Lambert argues that this decision compels dismissal of Plaintiffs' overall scheme claims "by expressly holding that different types of conduct, each of which is itself lawful under the antitrust laws, cannot be 'alchemize[d] ... into a new form of antitrust liability.'" Supplemental Memorandum Regarding Pertinent New Authority in Support of Defendants'

Motions to Dismiss the Complaints at 2, *In re Neurontin Antitrust Litig.*, No. 02-1390 (D.N.J. Mar. 23, 2009) ("Defendants' Supplemental Brief") (citing *Linkline*, 129 S. Ct. at 1123).

Warner-Lambert's arguments are not, however, supported by the bulk of prevailing case law on this issue. When determining antitrust liability based on a collection of factual allegations, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (citing *Continental Ore*, 370 U.S. at 699 ("In cases such as this, plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each. ... The character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole."); *see also City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect. ... We are dealing with what has been called the 'synergistic effect' of the mixture of the elements."). The distinction is between analyzing individual acts or categories of anticompetitive conduct as contrasted with individual theories of liability derived from those acts. Here, Plaintiffs' legal theory itself advances a monopolization scheme claim. If an antitrust plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions may trigger antitrust liability as an overall scheme.

Courts have routinely upheld the validity of "overall monopolization scheme" claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws. As the court noted in *Teva*

Pharmaceuticals, for example, "[p]laintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not." 432 F. Supp. 2d at 428.[38]

Indeed, this Court has previously allowed direct purchaser plaintiffs to pursue overall monopolization claims in a very similar context. In *Remeron*, the direct purchaser plaintiffs alleged that Organon undertook an overarching scheme to delay generic competition, and that the actions taken to further that scheme must be considered in their entirety. *Remeron*, 335 F. Supp. 2d at 528. Organon moved to dismiss the overall scheme claim, arguing that "because none of its actions individually was illegal, taken together they cannot constitute an 'overall scheme' to hinder competition," and citing to the same passages in *Intergraph* now relied upon by Warner-Lambert. *Id*.

This Court rejected those arguments. As noted in *Remeron*, "[t]he *Intergraph* court ... held that a group of *factual allegations* may be viewed in their totality, even while pieces of *legal theory* may not be added up and taken as a whole." *Id.* (emphasis in original). The Direct Purchaser Plaintiffs here are asserting one theory of liability - that Warner-Lambert has violated Section 2 of the Sherman Act by engaging in an overall scheme to monopolize the market for

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[38] *See also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (denying motion to dismiss antitrust counterclaims based on a "larger scheme to maintain [a] monopoly," because of the court's obligation to "consider the anticompetitive effect of [plaintiff's] acts as a whole," even though certain elements of the scheme did not independently produce an antitrust injury); *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952) ("The infringement action and the related activities, of course, in themselves were not unlawful, and standing alone would not be sufficient to sustain a claim for damages which they may have caused, but when considered with the entire monopolistic scheme which preceded them we think, as the trial court did, that they may be considered as having been done to give effect to the unlawful scheme."); *Biovail Corp.*, 49 F. Supp. 2d at 766.

gabapentin anhydrous. This theory is supported by a group of factual allegations, concerning several categories of allegedly anticompetitive conduct. In evaluating the sufficiency of Plaintiffs' pleadings in support of this theory of antitrust liability, "the relevant inquiry is the anticompetitive effect of the defendant's exclusionary practices considered together," and this Court "must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *Id*. (internal citations omitted).

The Court is not persuaded by Warner-Lambert's reliance on *Linkline* as a basis to set aside established law in "scheme" cases. The *Linkline* Court did not address the same issues facing this court, nor did that decision examine the precedents upon which Plaintiffs now rely. *Linkline* deals only with the viability of a prize squeeze claim in a particular factual situation and in a particular legal context.[39] The Court's rejection of a scheme claim in *Linkline* was mandated by the specifically applicable holdings in *Trinko* and *Brooke Group*. The *Linkline* Court did not discuss the sufficiency of other monopolization scheme claims, nor does anything in the *Linkline* decision indicate an intention on the part of the Court to overrule long-established principles

[39] The precise question presented to the Court in *Linkline* was "whether such a price-squeeze claim may be brought under § 2 of the Sherman Act when the defendant is under no antitrust obligation to sell the inputs to the plaintiff in the first place." In determining that no such claim may be brought, the Court relied primarily on *Verizon Communications Inc. v . Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004) (holding that a firm with no antitrust duty to deal with its rivals at all is under no obligation to provide those rivals with a "sufficient" level of service) and *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993) (establishing requirements for price squeeze claims, particularly concerning predatory pricing elements, and holding that the setting of retail prices above cost could not be predatory).

concerning the viability of claims alleging an overall scheme to unlawfully maintain a patent monopoly by excluding generic competition.[40]

Reviewing the allegations of anticompetitive conduct in their totality, it is clear that the Direct Purchaser Plaintiffs have adequately pled that Warner-Lambert engaged in a comprehensive multifaceted scheme to monopolize the market for gabapentin anhydrous; that the scheme was designed to obtain more market exclusivity for Neurontin than the patent laws allow; and that, as a result, Plaintiffs and other Neurontin purchasers were forced to pay higher prices for the drug. The Court need not determine whether the underlying elements of Plaintiffs' alleged scheme are violations of the antitrust laws in their own right. As the Supreme Court stated in the context of evaluating a Section 2 claim:

> It is not the form of the combination or the particular means used but the result to be achieved that the statute condemns. It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful. Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition.

American Tobacco Co. v. United States, 328 U.S. 781, 809 (1946). Accordingly, the Court finds that the Direct Purchaser Plaintiffs have adequately stated a claim for monopolization and

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[40] Indeed, when pressed by the Court at oral argument on the broader impact of the *Linkline* decision, counsel for Warner-Lambert acknowledged the he knew of no decisions applying the *Linkline* holding beyond the price squeeze context. *See* Transcript of Motion Hearing at 126-127, *In re Neurontin Antitrust Litig.*, No. 02-1390 (FSH) (Apr. 22, 2009) ("April 22 Transcript"). Plaintiffs' counsel contended that the Court would "have to rule that *Linkline* overruled *Continental Ore*" to apply *Linkline* in the broader fashion sought by Warner-Lambert. *Id*. at 130. Counsel continued that "there would have been quite a roar in the antitrust bar had people believed that *Linkline* had done that," and that the decision has not sparked such a reaction. *Id*.

attempted monopolization on the basis of allegations that Warner-Lambert has engaged in an overall scheme to monopolize the market for gabapentin anhydrous.

D. *Noerr-Pennington* Immunity And The Proper Scope Of The "Overall Scheme" Claim

Warner-Lambert also argues that certain of the anticompetitive acts alleged by Plaintiffs are immune from antitrust liability under the *Noerr-Pennington* doctrine. Such arguments require further consideration as conduct protected by *Noerr-Pennington* immunity cannot be properly included within the scope of the monopolization scheme alleged. *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) (holding that conduct that is protected from antitrust liability "is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.") ("*Pennington*"). Warner-Lambert asserts that its conduct in prosecuting the '482 Patent and its efforts to enforce the '476, '479, and '482 Patents against generic manufacturers through infringement actions are immune from antitrust liability such that all allegations based upon these activities must be dismissed.[41]

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[41] Warner-Lambert has not moved to dismiss the allegations of improper Orange Book listings on immunity grounds, arguing instead that any claims based on the improper listing of patents in the Orange Book fail because the listings were proper as a matter of law. This approach is consistent with case law establishing that the listing of patents in the Orange Book is not government petitioning as defined by the *Noerr-Pennington* doctrine and therefore not eligible for *Noerr-Pennington* immunity. *See In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002) ("*Buspirone*"); *Mylan*, 293 F. Supp. 2d at 458-59. Plaintiffs have also amply pled that Warner-Lambert obtained the Orange Book listings in question with sufficient anticompetitive purpose and effect. As a result, these allegations are properly considered within the scope of Warner-Lambert's alleged monopolization scheme.

Similarly, Warner-Lambert has not moved to dismiss the allegations of off-label marketing on immunity grounds. Rather, Defendants argue that "Plaintiffs' allegations of off-label marketing do not state an antitrust claim and should also be dismissed because, simply put, they have nothing to do with the relevant market or injury to competition plaintiffs allege." Defendants' Opening Brief at 50. Even taking such allegations as true, Warner-Lambert claims that its actions did not have an anticompetitive effect in the market defined by Plaintiffs in this

a. The *Noerr-Pennington* Doctrine And Its Exceptions

The *Noerr-Pennington* doctrine protects activities by parties to influence government policy or legislation from antitrust claims. *See Noerr*, 365 U.S. 127; *Pennington*, 381 U.S. 657. The doctrine nominally began as a judicially-created limitation on the scope of the Sherman Act with respect to activities by parties to petition the government to take a certain course of action beneficial to them and harmful to their competitors. It has since been extended to protect those who petition for other forms of governmental action. *See, e.g.*, *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972) (administrative and judicial proceedings); *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365 (1991) (municipal ordinances) ("*Omni*"). The doctrine has also been expanded to include litigation to protect rights such as patents. *See*

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proceeding, and cannot, therefore, violate the federal antitrust laws. While Plaintiffs may not be able to state an independent antitrust claim on the basis of their allegations of off-label marketing, each underlying element of the alleged monopolization scheme need not constitute an antitrust claim in its own right. To the extent that Plaintiffs have alleged that Warner-Lambert engaged in unlawful off-label promotional efforts in order to advance its overall monopolization scheme, such allegations survive the instant motion.

Nonetheless, while Warner-Lambert's marketing efforts may have helped build the market for gabapentin anhydrous, Plaintiffs must still prove that such actions were taken in furtherance and as an integral part of a plan to violate the antitrust laws, and that they actually contributed to the unlawful acquisition or maintenance of monopoly power in the market. Yet counsel for the Direct Purchaser Plaintiffs conceded at oral argument that these allegations to not advance Plaintiffs' scheme claims in the same way as certain other allegations, explaining that "[i]t's not the off-market labeling scheme per se [that] kept the generics off the market, although it was relevant to the '479 litigation...." April 22 Transcript at 189; *see also id.* at 226 ("I wouldn't say that it furthered the purpose of preventing generic competition, but what it did was a necessary part of succeeding on that scheme. Because otherwise the market wasn't - wasn't very large, it was a $200 million dollar market as opposed to a $2.5 billion dollar market. ... That's what made it worthwhile to do everything." Plaintiffs' ability to sustain their burden of proof on such issues is, however, better suited to resolution at the summary judgment or trial stages of this proceeding.

Professional Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993) ("*PRE*").

The *Noerr-Pennington* doctrine is not, however, without limit. The *Noerr* Court acknowledged that activity "ostensibly directed toward influencing governmental action" would not be immune from antitrust liability if it constituted "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Courts have held that activities in which the government entity merely plays a ministerial role, rather than making an independent determination, should not be afforded *Noerr-Pennington* immunity. *See Buspirone*, 185 F. Supp. 2d at 369-73; *Organon*, 293 F. Supp. 2d at 458-59. Litigation will not be protected when a court determines that it is "sham" litigation, i.e., instituted for the sole purpose of precluding competition. *PRE*, 508 U.S. at 60-61 (quoting *Noerr*, 365 U.S. at 144). And the "[f]raudulent procurement of a patent or the enforcement of a patent obtained by fraud may provide the basis for Sherman Act Section 2 liability if the other elements of a Sherman Act claim are present." *Remeron*, 335 F. Supp. 2d at 528 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965)).[42]

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[42] With respect to the scope and impact of the *Noerr-Pennington* doctrine, Plaintiffs also argue that it should not be used as an evidentiary rule to preclude the consideration of evidence of all actions taken by Warner-Lambert that are incidental to its scheme to restrain trade, even if certain actions are immunized and not considered to be an actionable part of the scheme itself. *See In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618 (E.D. Mich. 2000) (holding that "it is error for the court to treat the *Noerr-Pennington* doctrine 'as a rule of evidence that forbids the introduction of evidence … relating to efforts to obtain governmental protection' to show an antitrust violation."); *Hynix Semiconductor, Inc. v. Rambus, Inc.*, 527 F. Supp. 2d 1084 (N.D. Cal. 2007) (protected petitioning conduct may be considered by the court where it is causally connected to other anticompetitive activity). Accordingly, even if Warner-Lambert prevails on its *Noerr-Pennington* immunity arguments, evidence of any immune, yet allegedly

b. Patent Prosecution Misconduct

Plaintiffs allege that "[t]he '482 Patent was the end result of a long-running plan to delay the issuance of a patent claiming a low lactam formulation of gabapentin anhydrous until such time as that patent could be used to obtain a 30-month stay that would exclude generic competition beyond the stays already available through the '476 and '479 Patents." DPC Complaint ¶ 9. Rather than aggressively prosecuting the patent, "Defendant took great pains to prolong the continued prosecution of the 'low lactam' patent application, so that the patent issued at a time when the 30-month stay in connection with patent litigation could be used to further delay generic competition." *Id*. ¶ 11. Plaintiffs claim that Warner-Lambert purposefully withdrew the approved application for this patent shortly before it was scheduled to issue because issuing the patent in 1995 "would not have provided any additional protection than was already possible through Defendant's misuse of the '476 and '479 patents." DPNC Complaint ¶ 54. Plaintiffs further argue that Warner-Lambert's strategic manipulation of the patent approval process was an integral part of Warner-Lambert's overarching monopolization scheme, "permitting Defendant to artificially prolong the period during which it could bring patent infringement litigation and thereby take advantage of the Hatch-Waxman 30-month stay." Plaintiffs' Opposition Brief at 64.

Warner-Lambert counters that its prosecution of the '482 Patent is immune from antitrust liability under the *Noerr-Pennington* doctrine because its "prosecution at the PTO to obtain the

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anticompetitive, conduct may still be relevant to an evaluation of Warner-Lambert's anticompetitive scheme, if such conduct is causally linked to the scheme. This footnote is not an evidentiary ruling. A motion *in limine*, at the appropriate time, may be made. If the evidence is ruled admissible, a limiting instruction to the jury should amply protect Warner-Lambert if such evidence is admitted at a jury trial.

patent constituted classic petitioning of the government that is immune under *Noerr*." Defendants' Opening Brief at 25. Defendants claim that other than sham litigation, only the commission of fraud within the meaning of *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp*. "is sufficient to strip a patentee of its immunity from the 'antitrust laws.'" *Id*. at 26. Accordingly, Warner-Lambert urges that any claims based on allegations of misconduct during the prosecution of the '482 Patent must be dismissed.

Under the *Walker Process* doctrine, the "[f]raudulent procurement of a patent or the enforcement of a patent obtained by fraud," although an act or result of government petitioning, may provide the basis for antitrust liability. *Remeron*, 335 F. Supp. 2d at 528. To establish a *Walker Process* claim of fraud, an antitrust plaintiff must show: "(1) [a] false representation or deliberate omission of a fact material to patentability (2) made with the intent to deceive the patent examiner (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted." *Id*. (quoting *C.R. Bard*, 157 F.3d at 1364).

Warner-Lambert argues that, "[s]imply put, the delay plaintiffs allege was not fraudulent, and the antitrust laws do not 'reach ... monopolies carried on under a nonfraudulently procured patent." Defendants' Opening Brief at 26 (citing *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069 (Fed. Cir. 1998) ("*Nobelpharma*")). Defendants emphasize that courts have frequently drawn a distinction between "patents procured by 'deliberate fraud' and those rendered invalid or unenforceable for other reasons." *Nobelpharma*, 141 F.3d at 1069 (internal citations omitted). Only the former, they argue, are subject to antitrust liability. Plaintiffs' ability to pursue antitrust claims would, therefore, not reach "monopolies practiced under patents

that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent." *Id*. Although Plaintiffs here may have alleged inequitable conduct before the Patent Office, their allegations of delay do not establish *Walker Process* fraud and thus must be dismissed.

However, Plaintiffs here have not pled a classic *Walker Process* claim, and they do not claim that the intentionally delayed prosecution of the '482 Patent renders the patent itself invalid. Rather, Plaintiffs challenge Warner-Lambert's strategic manipulation of the patent approval process with the alleged goal of restraining competition. They allege that Warner-Lambert fraudulently delayed the issuance of the patent by deliberately making a "mistake" in its disclosure statements which then achieved delay when Warner-Lambert sought to "correct" its filings. The *Noerr-Pennington* doctrine does not, Plaintiffs argue, "provide a safe harbor" for such conduct. Plaintiffs' Opposition Brief at 64.[43]

The Court agrees. Rather than implicating the *Walker Process* exception to *Noerr-Pennington* immunity, their allegations can be viewed as the equivalent of a more generalized "sham" or "sham petitioning" exception. The *Noerr* Court did not immunize activities which are

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[43] Plaintiffs also argue that the prosecution of the '482 Patent is not entitled to *Noerr-Pennington* immunity because the withdrawal of a patent from PTO consideration is a ministerial function to which the *Noerr-Pennington* doctrine does not apply. They explain that the PTO was obligated to withdraw the pending patent application when Warner-Lambert requested the withdrawal. According to Plaintiffs, "[b]ecause the conduct at issue here amounted to a manipulation of the patent system outside the discretionary authority of the PTO, Defendant's withdrawal of the originally approved low lactam patent and dilatory prosecution of the '482 patent is not 'petitioning' within the meaning of *Noerr-Pennington*." Plaintiffs' Opposition Brief at 69.

Plaintiffs' allegations concern more than the withdrawal of the pending patent application, focusing instead on the prosecution process as a whole. Plaintiffs' antitrust allegations concern this broader process and the Court will not isolate one step in an allegedly corrupted overall process as determinative of the question of *Noerr-Pennington* immunity.

"ostensibly directed toward influencing governmental action" but which are, in fact, shown to be "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Sham petitioning "encompasses situations in which persons use the governmental *process* - as opposed to the *outcome* of that process - as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay." *Omni*, 499 U.S. at 380 (citing *Cal. Motor Transp.*, 404 U.S. 508) (emphasis in original). Under this exception to *Noerr-Pennington* immunity, proof of "a pattern of baseless, repetitive claims" may lead "the factfinder to conclude that the administrative and judicial processes have been abused. ... actions of that kind cannot acquire immunity by seeking refuge under the umbrella of 'political expression.'" *Cal. Motor Transp.*, 404 U.S. at 513.

While not expressly claiming this "sham petitioning" exception, Plaintiffs' Complaints contain factual allegations which, if proven, are sufficient to warrant an exception to *Noerr-Pennington* immunity under this theory. Plaintiffs have clearly alleged that Warner-Lambert manipulated the prosecution of the '482 Patent, not to promptly obtain government action in its favor, but rather to delay its issuance and thereby forestall generic competition for Neurontin by obtaining 30-month stays barring generic products from the market. Specifically, Plaintiffs have pled that Warner-Lambert, acting with the specific intent to monopolize or maintain its monopoly in the gabapentin anhydrous market, withheld prior art, filed unnecessary continuation applications, and abandoned an approved patent application in an attempt to obtain successive, rather than concurrent, 30-month stays. They have further alleged that the delays resulting from

this sham petitioning kept prices for the drug higher than they would have been in a competitive marketplace. These actions were, moreover, allegedly an integral part of Warner-Lambert's overall monopolization scheme. If such allegations are proven, Warner-Lambert's patent prosecution gamesmanship could reasonably be considered "nothing more than an attempt to interfere directly with the business" of Warner-Lambert's generic competitors. The Court does not declare such conduct immune as a matter of law at this stage of the litigation.

Courts have already held that abuse of the patent prosecution process and inequitable conduct before the Patent Office similar to what is alleged here may form the basis for a viable antitrust claim. In *DiscoVision Associates v. Disc Manufacturing, Inc.*, the court denied a motion to dismiss Disc Manufacturing's monopolization claim based on, among other things, allegations that DiscoVision "committed fraud and misrepresentations in prosecuting its patents" and "committed these acts and filed continuation applications with the specific intent to monopolize or maintain its monopoly" in the relevant markets. *DiscoVision Assoc.*, 1997 WL 309499, at *8. Disc Manufacturing had also alleged that DiscoVision had "employ[ed] improper delaying tactics in the PTO," and had "purposefully withheld material prior art during the prosecution of applications that led to" some of the patents at issue in the lawsuit. *Id*. at *3. The court concluded that "[t]hese allegations, if true, are sufficient to support the inference that DiscoVision's continuation applications had an anticompetitive effect beyond the grant of the patent ... [and] may form a basis for antitrust liability." *Id*. at *8. Plaintiffs here have made comparable allegations concerning Warner-Lambert's actions in prosecuting the '482 Patent.

Similarly, in denying a motion to dismiss antitrust claims based on the "late listing" of patents in the Orange Book, this Court held that:

> Within the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market. ... At this stage in the instant action, it cannot be said to a legal certainty that no relief could be granted under Section 2.

Remeron, 335 F. Supp. 2d at 532.

The same principles apply to the conduct alleged in this proceeding. The Hatch-Waxman regulatory scheme presents unique opportunities for gamesmanship by offering a "non-refundable" 30-month stay. It remains to be seen whether the evidence will bear out the claims that Warner-Lambert manipulated the process and timing of patent prosecutions in order to expand the otherwise lawful monopoly granted to it by a patent or a series of patents. Fraudulently delaying the issuance of a patent could lead to anticompetitive effects in the relevant market if such delays were intended to obtain control over or exclude competitors from that market via Hatch-Waxman's 30-month stay provisions. As Plaintiffs argue, granting immunity to such conduct would run counter to the public policies underlying the *Noerr-Pennington* doctrine. Abuse of the Patent Office's administrative and regulatory process itself is not entitled to immunity.

In sum, the Direct Purchaser Plaintiffs have adequately alleged facts which, if proven, will show that Warner-Lambert's prosecution of the '482 Patent was conducted in a manner that was "ostensibly directed toward influencing governmental action," but was really meant "to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. The conduct alleged may form the basis for antitrust liability outside of the *Walker Process* framework if Plaintiffs can establish the remaining requirements under Section 2. Plaintiffs' allegations that Warner-Lambert unlawfully manipulated the patent approval process for the '482

Patent will not, therefore, be dismissed as immune and can properly be considered within the scope of Warner-Lambert's alleged overall scheme to monopolize the gabapentin anhydrous market.[44]

c. Sham Infringement Actions

Plaintiffs allege that Warner-Lambert "responded to the attempts of generic manufacturers to obtain approval of generic equivalents with an aggressive policy of filing infringement cases to enforce the '476, '479 and '482 patents." DPNC Complaint ¶ 63. These lawsuits were not, Plaintiffs claim, legitimate efforts to protect Warner-Lambert's patent rights. Rather, "[e]ach of these patent infringement lawsuits was objectively baseless and intended solely to illegally extend [Warner-Lambert's] monopoly by delaying the entrance of generic manufacturers into the gabapentin anhydrous market." *Id*. Warner-Lambert asserts that any antitrust claims based on its patent infringement actions fail, because the underlying lawsuits are entitled to immunity from antitrust liability under *Noerr-Pennington*.

Warner-Lambert correctly argues that litigation to enforce its rights under its gabapentin patents is presumptively immune from antitrust scrutiny under the *Noerr-Pennington* doctrine. However, Warner-Lambert is not entitled to such immunity if Plaintiffs can establish that the '476, '479, and '482 infringement actions were "sham litigation." The Supreme Court has established the following test for sham litigation:

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[44] Plaintiffs argue that "discovery will prove that this delay was part of a wrongful scheme to achieve the extra exclusivity period and not part of legitimate petitioning activities as contemplated by *California Motor Transport*." Plaintiffs' Opposition Brief at 66-67. If, after discovery, such evidence is not adduced, and Plaintiffs are unable to meet their burden of proof as to the sham exception, Warner-Lambert may renew its claims for *Noerr-Pennington* immunity.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor."

PRE, 508 U.S. at 60-61 (quoting *Noerr*, 365 U.S. at 144). The outcome of this analysis is determined, in large part, by a court's finding that the antitrust defendant had probable cause to initiate the litigation being challenged as sham.[45]

Warner-Lambert argues that this issue is ripe for decision by this Court as a matter of law at this relatively early stage of the antitrust litigation, emphasizing that *PRE* holds that where "there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law." *Id*. at 63. Warner-Lambert sets forth a series of earlier rulings that it argues clearly establish that its infringement claims were not objectively

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[45] As the Supreme Court further explained in *PRE*:

> The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings, requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose. Probable cause to institute civil proceedings requires no more than a "reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication." ... When a court has found that an antitrust defendant claiming *Noerr* immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit. Under our decision today, therefore, a proper probable cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noerr* immunity.

Id. at 62 (internal citations omitted).

unreasonable, thereby also establishing the existence of probable cause and precluding a determination that such claims were objectively baseless.[46]

Plaintiffs, however, contend that they have adequately alleged that the lawsuits concerning each of the three patents at issue were objectively baseless and that no reasonable litigant could have expected success. Specifically, Plaintiffs assert that Defendants knew or recklessly disregarded the fact that the '476 Patent did not cover the drug that generic manufacturers sought to manufacture and market, yet still initiated infringement actions. With respect to the '479 Patent actions, Plaintiffs claim that Warner-Lambert brought suit against the

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[46] In support of this argument, as it pertains to the '476 and '479 infringement actions, Warner-Lambert cites a long list of prior rulings: (1) *Warner-Lambert Co. v. Purepac Pharm. Co.,* Nos. 98-2749, 98-5948, 2003 WL 21698310, at *1 (D.N.J. May 22, 2003) (stating on denial of a motion for attorneys' fees that "there is insufficient evidence to support a conclusion that Warner-Lambert's claim of infringement was unreasonable or that its listing in the Orange Book was improper."); (2) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 2003 WL 21754948, at *4 (N.D. Ill. July 28, 2003) (rejecting a motion for fees and Rule 11 sanctions and observing that Warner-Lambert "had a reasonable basis to think that it would ultimately discover that Teva performed some step in the production process" that would support an infringement claim); (3) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 2003 WL 22887861, at *4-5 (N.D. Ill. Dec. 4, 2003) (affirming the rejection of fees and sanctions, noting that "TorPharm has not demonstrated that Warner-Lambert initiated a frivolous suit with respect to this claim," and that Warner-Lambert "had the right to conduct a fair and reasonable investigation of its claims [in discovery]."); (4) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 1999 WL 259946, at *3, *6 (N.D. Ill. Apr. 8, 1999) (denying a motion for summary judgment because Warner-Lambert was "perfectly entitled" to proceed under a theory of inducement and had submitted sufficient evidence to avoid summary judgment); and (5) *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 98-2749, slip. Op. at 7-8 (D.N.J. Aug. 26, 1999) (denying summary judgment on the inducement claim because there were genuine issues of fact as to "whether Purepac will knowingly and actively induce infringement of the patent.").

Warner-Lambert relies on the litigation record concerning the '482 Patent in a similar fashion, arguing that the record establishes as a matter of law that the infringement actions were not sham. In particular, Warner-Lambert emphasizes that it "won nine of ten summary judgment motions and defeated summary judgment of non-infringement with respect to four of five defendants." Defendants' Opening Brief at 9. *See, e.g.*, *In re Gabapentin Patent Litig.*, 2005 WL 2654362 (D.N.J. Aug. 25, 2005); *In re Gabapentin Patent Litig.,* 395 F. Supp. 2d 140 (D.N.J. 2005).

generic manufacturers without evidence of knowledge and intent to induce infringement, while knowing that none of the generic applicants sought approval to market generic gabapentin to treat neurodegenerative diseases. Finally, Plaintiffs argue that they have sufficiently alleged that "no reasonable litigant would believe that the ['482 Patent's claims] could ultimately be upheld as valid, definite, and/or infringed," "[b]ecause of the inability to measure chloride ions from a mineral acid at the low levels specified by the '482 Patent, or to distinguish the level of chloride ions from a mineral acid in the claim from the prior art." Plaintiffs' Opposition Brief at 56.

Plaintiffs also argue that none of the court opinions identified by Warner-Lambert compel dismissal of their claims. Although "the Court may take judicial notice of the opinions filed in the underlying actions ... the scope of that notice is subject to important limitations. The Court may take judicial notice only of the 'existence of the opinion, which is not subject to reasonable dispute over its authenticity.'" *Wellbutrin*, 2006 WL 616292, at *6 (quoting *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999)). The Court is not, however, permitted to "make factual findings in this case based on the facts recited in the opinions of other courts." *Id*.

Surviving summary judgment does not, alone, establish that a lawsuit is not sham for the purposes of an antitrust claim. Judge Lifland, for example, was presented with this exact argument in one of Warner-Lambert's early suits against Purepac. Rather than relying on a previous summary judgment opinion, he determined that a "summary judgment denial, in and of itself, cannot deem litigation objectively reasonable without specific examination of the basis for denial of summary judgment." December 22 Opinion, 2000 WL 34213890, at *5. He further concluded that the denial of summary judgment in one proceeding "does not necessarily relate to

the asserted basis for antitrust relief" in another, suggesting that courts must consider whether claims of sham litigation and overall antitrust violations are premised on a broader range of facts and issues. *Id*.[47]

Furthermore, when the predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law. *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 361 (D. Mass. 2004) (finding that "'the facts tending to establish the existence or want of existence of probable cause' were disputed, rendering the question inappropriate for decision as matter of law," despite summary judgment decisions in the underlying patent proceedings) (quoting *Nelson v. Miller*, 227 Kan. 271, 277 (1980)). At this stage of the litigation, the Court's probable cause analysis is based exclusively on the allegations in Plaintiffs' Complaints. *Jarrow Formulas, Inc. v. Int'l Nutrition Co.*, 175 F. Supp. 2d 296, 310-11 (D. Conn. 2001) ("Here, all that is required is that the complaint allege facts, which, if proven, show that the defendant is not entitled to *Noerr-Pennington* immunity under the sham litigation exception."); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 10 (D. Mass. 1994) ("Because [the defendant's] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the

[47] Counsel for Louisiana Wholesale further elaborated upon this issue at oral argument. Relying on decisions issued in *In re Relafen Antitrust Litig.*, counsel emphasized that a pioneer drug manufacturer's patent infringement lawsuit cannot be deemed objectively reasonable simply by surviving the summary judgment stage, "if the facts ... offered to the patent judge to beat summary judgment were based on misrepresentations." April 22 Transcript at 213. Plaintiffs here allege that the decisions on which Warner-Lambert now relies were based on similar misrepresentations, such that those decisions cannot be used to determine that the underlying lawsuits were objectively reasonable as a matter of law.

business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6).").[48]

Courts have rejected claims of *Noerr-Pennington* immunity made through motions to dismiss in situations similar to that now before this Court. In *Hoffman-LaRoche, Inc. v. Genpharm, Inc.*, for example, the court determined that:

> The resolution of the question whether plaintiffs' suit is objectively baseless as to Genpharm involves the determination of whether plaintiffs undertook a reasonable investigation before filing suit, whether plaintiffs knew or should have known that Genpharm had not infringed the Syntex process patents, and whether a reasonable litigant could have realistically expected success on the merits at the time the suit was filed. Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.

50 F. Supp. 2d 367, 380 (D.N.J. 1999).

Plaintiffs have raised similar factual questions about whether Warner-Lambert examined or tested the proposed generic products before initiating litigation, and whether and when Warner-Lambert knew that certain generic products were manufactured outside of the United States and thus not subject to patent infringement liability. This Court cannot now look to the

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[48] *See also Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251, 2008 WL 2967034, at *7 (D.N.J. July 31, 2008) (holding that defendant had sufficiently alleged the elements necessary to plead sham litigation and that, as a result, plaintiff was not entitled to immunity at the "preliminary stage of the action," but explaining that "upon litigation of the patent infringement claims and upon discovery as to Defendant's Counterclaims, if Defendant does not bear its burden of proof as to a 'sham' litigation, Plaintiff may seek anew *Noerr-Pennington* immunity.").

Despite such case law, many of Warner-Lambert's arguments address the merits of Plaintiffs' claims, rather than the sufficiency of their pleadings. For example, Warner-Lambert asserts that the specific allegations made about the '482 Patent fail to establish the objective baselessness of the '482 infringement actions. Plaintiffs need not establish objective baselessness at this point, they need only allege facts which will establish objective baselessness, and the other elements of the sham litigation exception to *Noerr-Pennington* immunity, if they are subsequently proven. Plaintiffs here have satisfied that standard. To the extent that Warner-Lambert's arguments address the merits of whether its infringement actions were, in fact, sham, the Court reserves judgment until the summary judgment stage of this proceeding.

basis for lines included in other courts' rulings on matters such as sanctions and attorneys' fees to ascertain what analysis was done on the above-enumerated factors; what each court knew or did not know about the full panoply of the litigation; nor what claims were asserted in those cases about the objective reasonableness, or lack thereof, of the infringement actions brought by Warner-Lambert. As a result, the Court cannot make a determination about the existence or want of probable cause for Warner-Lambert's infringement actions upon the pending motions to dismiss but will rather reserve judgment on such issues until motions for summary judgment are made.

Plaintiffs' allegations that Warner-Lambert pursued litigation against generic applicants as an attempt to unlawfully maintain control of the market for gabapentin anhydrous will not, therefore, be dismissed and can properly be considered within the scope of Warner-Lambert's alleged overall scheme to monopolize the gabapentin anhydrous market.[49]

V. Conclusion

For the reasons set forth in this Opinion, the Court denies Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Claims. An appropriate Order will issue.

s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.

[49] The Court notes, however, that after litigation of Warner-Lambert's patent infringement claims in the related patent proceedings and upon discovery in this proceeding, if Plaintiffs do not adduce evidence sufficient to sustain their burden of proof as to the sham exception, Warner-Lambert may renew its claims for *Noerr-Pennington* immunity.